UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

February 27, 2015

**MEMORANDUM**

SUBJECT: Efficacy Review for Accel Concentrate Disinfectant Cleaner;
EPA Reg. No, 74559-4;
DP Barcode: D423917

FROM: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
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3.3.15

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TO: Demson Fuller, PM 33/ Terria Northern
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APPLICANT: Virox Technologies, Inc
2770 Coventry Road
Oakville, Ontario L6H 6R1

FORMULATION FROM LABEL:

| Active Ingredient(s) | % by wt. |
|---|---|
| Hydrogen Peroxide | 4.25% |
| Inert Ingredients | 95.75% |
| Total | 100.00% |

## I BACKGROUND

The product, Accel Concentrate Disinfectant Cleaner (EPA Reg. No. 74559-4), is a one-step disinfectant cleaner, deodorizer with virucidal and fungicidal label claims. This submission is to add a new Virucidal label claim for Porcine Epidemic Diarrhea Virus. A single Virucidal efficacy study was submitted. The study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated October 28, 2014), one study (MRID 494930-01), Statements of No Data Confidentiality Claims for the study, and the proposed label.

## II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, in healthcare settings, office buildings, schools, colleges, day care centers, funeral homes, animal life sciences laboratories, hotels, motels, foodservice establishment and other industrial and commercial areas. It is designed to treat the following surfaces. Vinyl, painted surfaces, plastic glass, mirrors, glazed ceramic, toilets, floors, walls, ceilings, sinks, sink basins another hard, non-porous non-food contact surfaces.

As a disinfectant: When used as directed, this product is highly effective against a wide variety (broad spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew). At a 1:16 to 1:64 dilution (2-8 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 5 minute contact time, unless otherwise noted.

As a fungicide: Use at 1:16 dilution (8 oz. per gallon of water), and in the presence of a 5% serum load and five minute contact time at 20°C (68°F).

To Sanitize Non-Food Contact Surfaces: Dilute 1.0 oz. of product per gallon of water (1:128). Pre-clean heavily soiled hard non-porous surfaces. Apply Use Solution until thoroughly wet. Let stand for 3 minutes. Wipe surfaces (and let air dry).
Not for use on food contact surfaces or on food preparation areas.
Note: Do not use on glassware, utensils or dishes.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the

virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

## IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

**MRID 494930-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Porcine Epidemic Diarrhea Virus," Product Identity: Accel Concentrate Lot # 10624 and Lot # 10625, by Shanen Conway, Study conducted at ATS Labs. Study completion date – September 22, 2014. Project Number: A16900**

This study was conducted against Porcine Epidemic Diarrhea Virus (Colorado 2013 isolate strain) was obtained from the National Veterinary Services Laboratories, Ames, Iowa. Two lots of the product (Lot #s 10624 and 10625) Accel Concentrate were tested using Protocol Number VIR07060314.PEDV.1 (copy provided). The product was tested at a 1:64 dilution (defined as 1 mL test substance + 64.0 mL 200 ppm AOAC synthetic hard water). Fetal bovine serum was added as an organic soil load to a concentration of 5%. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of three separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 30% relative humidity. For the product lots, a dried virus film was exposed to 2.00 mL of the use solution for 5 minutes at 20.0°C. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed immediately through Sephadex columns. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity or cytotoxicity. The Vero 76 cell line, which exhibits CPE in the presence of Porcine Epidemic Diarrhea Virus, was used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes were inoculated in quadruplicate with 0.2 mL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36 - 38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for seven days for the presence or absence of CPE, cytotoxicity, and for viability.

Note: Protocol deviations/amendments reported in the study were reviewed.

## V RESULTS

| MRID Number | Organism | Results | | Dried Virus Count |
|---|---|---|---|---|
| | | | Lot Nos. 10624 & 10625 | |
| 494930-01 | Porcine Epidemic Diarrhea Virus | $10^{-1}$ to $10^{-6}$ dilutions | Cytotoxicity | $\geq 10^{5.50}$ $TCID_{50}$/0.2 mL |
| | | $TCID_{50}$/0.2 mL | $\leq 10^{0.5}$ | |

## VI CONCLUSIONS

### A. Conclusions Regarding Use of the Product as a Disinfectant

1. The cited efficacy data support the use of the product, Accel Concentrate Disinfectant Cleaner, as a disinfectant with virucidal activity against the following microorganism on hard, non-porous surfaces at a 1:64 dilution in 200 ppm hard water and in the presence of a 5% organic soil load for a 5-minute contact time:

Porcine Epidemic Diarrhea Virus MRID 494930-01

Acceptable virus counts were achieved. Acceptable control results were achieved.

## VII RECOMMENDATIONS

1. The proposed label claims that a 1:16-1:64 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective disinfectant against the following microorganism on hard, non-porous environmental surfaces in the presence of 200 ppm hard water and 5% serum for the contact times listed:

Porcine Epidemic Diarrhea Virus 5 minutes

These claims **are acceptable** as they are supported by the cited data